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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,517	08/17/2005	Hans W. Schmid	2923-709	2282

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
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WASHINGTON, DC 20005

EXAMINER
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MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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08/07/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	Application No. 10/533,517	Applicant(s) SCHMID, HANS W.	
	Examiner Melissa S. Mercier	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5-2-05, 7-17-07</u> . | 6) <input type="checkbox"/> Other: ____  |

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## **DETAILED ACTION**

### ***Priority***

Applicants claim of priority to Application 10/353,056 filed on January 29, 2003 is acknowledged.

### ***Information Disclosure Statement***

Receipt of the Information Disclosure Statements filed on May 2, 2005 and July 17, 2007 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently

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distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

While the specification describes a species of the instantly claimed melatonin and/or melatonin derivatives, preferred melatonin derivatives include, for example, 5-methoxytryptamine, 5-methoxytryptophan, 5-methoxytryptophol, 5-methoxy-indole-3-acetic acid and 6-hydroxymelatonin on p.1-2, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by derivatives.

Claim 10 is additionally rejected for the recitation of "derivatives of Vitamin A". The specification does not describe a species of the instantly claimed derivatives to convey possession of the genus.

### ***Claim Rejections - 35 USC § 103***

Claims 1-22 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dirksing et al (US 5,006,004) in view of Samples et al. (US Patent 4,654,361) and Kosbab (US 2001/0031744) or vice versa, Samples et al in view of Kosbab and further in view of Dirksing et al.

Dirksing et al. discloses a single-use disposable dispenser for the application of a liquid formulation, such as a hair loss treatment (cols. 1-2). The reference teaches a design for the disposable dispenser that comprises a compressible reservoir and a non-porous application tip (col. 2, 14-16). The dispenser is made of plastic materials such as polyethylene or polypropylene (col. 3, 60-61). The disposable container is opened by

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twisting the closure tab (col. 6, 25-29). The reference also teaches that the any suitable drug can be contained in the dispenser (col. 7, 5-8).

The reference does not disclose the specific active ingredient or formulation of the instant claims. It does not teach the specific volume requirements of the instant claims. It also does not teach the specific colors, or embossed lettering on the packaging as of the instant claims.

Samples discloses a method of lowering the intraocular pressure in a human by administering melatonin (abstract). The melatonin can be administered topically and in therapeutically effective amounts of about 20 micrograms to 200 milligrams a day (column 2, lines 34-42). Samples further discloses the melatonin is administered as a single daily dosage (column 2, lines 21-22).

Samples does not disclose the use of biotin, ginkgo biloba or vitamin A.

Kosbab discloses "a treatment of degenerative ocular conditions such as macular degeneration, cataracts and glaucoma with a composition comprising a plant extract having antioxidant effect comprising bioflavanoids, for example, ginkgo biloba" (paragraphs 0019-0021). Vitamin A is also disclosed as a treatment of ocular conditions (paragraph 0045).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the disposable tubes disclosed by Dirksing to administer the combined topical composition of Samples and Kosbab because Dirksing teaches that the tubes can be used to topically apply a liquid composition. One of ordinary skill in the art would be motivated to add the topical melatonin composition for

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the treatment of the eye taught by Samples and Kosbab with the to the disposable, plastic, liquid container with a compressible liquid reservoir and a twist off seal to arrive at a disposable single dose dispenser containing melatonin for topical application.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the plant extract and vitamins taught by Kosbab with the melatonin composition taught by Samples since both references disclose treatments for the eye. Gingko biloba is known in the art for its antioxidant activity and a deficiency of Vitamin A is known in the art to cause night blindness and inflammation of the eyes (xerophthalmia), followed by irreversible blindness.

Claims 23-25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dirksing et al. (US 5,006,004) in view of Samples et al (US 4,654,361), Kosbab (US2001/0031744), and Fukuoka (US 5,577,636) or vice versa.

The combination of Dirksing, Samples and Kosbab are discussed above and applied in the same manner.

Dirksing does not teach the limitation of multiple containers being attached to each other in a detachable manner and packaged together as a unit. One of ordinary skill in the art would look to the prior art for a teaching of how to connect single use containers to one another in a detachable manner.

Fukuoka teaches a multi-tube container comprising multiple tubes that are breakable attached to each other (see abstract, and Figures 1-9).

Thus it would have been obvious to one of ordinary skill in the art to make a

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multiple tube containers that contains tubes that are detachably attached to one another because this form of a container is well known in the art and is taught by Fukuoka.

### ***Double Patenting***

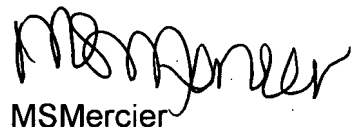
Claims 1-29 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 5-7, 9-30 of copending Application No. 10/353,056. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

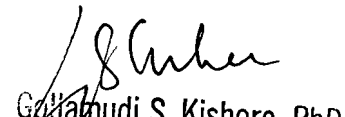
No claim is allowable. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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